PATENT
Atty docket no.: 0402-UTL-5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
GEDULIN *et al.*
Appln. No. 10/518,128
I.A. Filing Date: June 13, 2003
371 Date: August 29, 2005
For: **Prevention and/or Treatment of Inflammatory Bowel Disease Using PYY or Agonists Thereof**

Group Art Unit: 1646
Examiner: LI, RUIXIANG
Confirmation No.: 7370

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Document(s)	**No. of Pages**
Response to Restriction Requirement	**5**

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RESPONSE TO THE RESTRICTION REQUIREMENT

Mail Stop: **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The present Response is filed in regard to the Restriction Requirement mailed 23 March 2006 in connection with the above-identified patent application. Because the one-month deadline for response falls on a Sunday, this response, dated 24 April 2006, is timely filed.

As a preliminary matter, Applicants wish to clarify that claim 4 was canceled in the preliminary amendment of 29 August 2005, and that the claims pending in this application are 1-3 and 5-21. Applicants also wish to bring to the Examiner's attention co-pending U.S. applications 10/016,969, 11/055,098 and 11/301,744 assigned to Amylin Pharmaceuticals, Inc., and applications 09/499,526 and 10/855,676, licensed to Amylin Pharmaceuticals, Inc.

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The Examiner has restricted claims 1-21 into two groups. According to the Examiner's restriction, the Group I claims 1-14 are drawn to a method of treating intestinal damage comprising administering PYY or a PYY agonist, and the Group II claims 15-21 are drawn to a method of treating a bowel condition comprising administering a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist. Applicants hereby provisionally elect Group I containing claims 1-14 with traverse.

Applicants respectfully traverse the Restriction Requirement by the Patent Office. Applicants respectfully submit that claims 1-3 and 5-21 are improperly restricted, because the Examiner is not applying the proper Unity of Invention standard. The Examiner mistakenly asserts that invention Groups I and II do not share a special technical feature. (See last paragraph on page 2 of the Office Action). Applicants disagree. Under PCT Rules 13.1 and 13.2, and 37 C.F.R. § 1.475, a national stage application "shall relate to one invention only or to a *group of inventions so linked as to form a single general inventive concept.*" (Emphasis added). Applicants respectfully submit that the inventions are so linked and form a single general inventive concept. All of the pending claims are directed to a product a PYY or PYY agonist, and a process of using the product, i.e., methods of treating an intestinal condition with a PYY or PYY agonist. In particular, all of the claims have the special technical feature of requiring PYY or a PYY agonist. The process claims share the general inventive concept that the PYY or PYY agonist is administered directly or indirectly (through the use of a probiotic bacterium comprising a nucleic acid encoding a PYY or PYY agonist) to treat bowel conditions (for example, intestinal damage).

PCT Rule 13.2 explicity states that the requirement of Unity of Invention is to be considered fulfilled when:

> "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

Furthermore, 37 C.F.R. § 1.475 states that "(a)n international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: ...(2) A product and process of use of said product ..." The claims of the instant invention fall within category (2) above, because they are directed to a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist (a product), and methods of treating bowel conditions, for example intestinal damage, comprising administering PYY or a PYY agonist (process of use).

Citing *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. Va. 1986), the M.P.E.P § 1850, section I explains that, in the examination of an international application, it is improper to restrict claims directed to a process of using an apparatus from claims drawn to the apparatus based on a lack of unity of invention. M.P.E.P § 1850 states:

> "when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111."

Thus, the Examiner is required to apply the International unity of invention standard without regard to U.S. restriction practice.

Referring to claims 7 and 8, which recite administration of a growth hormone and an anti-inflammatory agent, respectively, the Examiner also alleges that the application contains claims directed to more than one species of the generic invention, and that these species lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 (page 3, section 3 of the Office Action). Applicants disagree. However, in accordance with 35 U.S.C. § 121, Applicants hereby provisionally elect an anti-inflammatory agent with traverse.

The Examiner alleges that a growth hormone of claim 7 and an anti-inflammatory agent of claim 8 "lack the same or corresponding special technical features" and that "all alternatives of a Markush group must have a common structure." First, under the PCT Rules, there is no provision for an election of species. Second, the relevant section of the guidelines in Section (f) of Annex B of the PCT administrative instructions provides:

> "the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) All alternatives have a common property or activity..."

The application describes growth hormones and anti-inflammatory agents as "other therapies" that may be used to treat inflammatory bowel disease, and which may be co-administered with PYY or a PYY agonist (See page 5, line 24 through page 6, line 2 of the Specification), indicating that they share a common property or activity. Thus, these elements of claims 7 and 8

do not lack unity of invention, as they have a "technical interrelationship," and should be examined together.

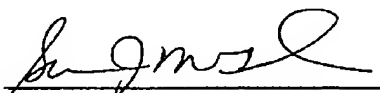
In light of the above arguments, Applicants' elections of Group I and an anti-inflammatory agent are provisional, with traverse, and Applicants respectfully request that the restriction requirement and election of species be reconsidered and withdrawn.

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. §§ 121 and 372. Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to answer such questions or provide additional information.

No fees are believed due for this submission. If a fee is due, or becomes due at any time during the pendency of this application, the Commissioner is hereby authorized to charge any fees associated with this communication or credit any overpayment to Applicants' Deposit Account No. 010535.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

Dated: 24 April 2006

By: 
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